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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,787	06/26/2001	Carl Nelson Skold		4399

7590 09/10/2004

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EXAMINER

DO, PENSEE T

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/891,787

Applicant(s)

SKOLD, CARL NELSON

Examiner

Pensee T. Do

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 24, 2004 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 54, 55, 57-62, 66, 68, 69, 73-75 are rejected under 35 U.S.C. 102(b) as being anticipated by Molday (US 4,452,773).

Molday teaches a method of separating a target material from a suspension or dispersion, said method comprising the steps of: combining magnetizable particles composed of magnetic iron oxide coated with a polysaccharide, preferably dextran, or a derivative thereof having pendant functional groups with a suspension containing a target binding material for said target material to bind to said magnetizable particles; and applying a magnetic field to said suspension or dispersion to separate the magnetizable particles and target material. The target binding material is an antigen,

Art Unit: 1641

antibody, or nucleic acid. The target material is a biological material. The magnetic particles have a particle size of about 100 to 700 Angstrom. (see col. 3, lines 14-22). The purified complex of magnetizable particles bound to said target material is dissociated and said magnetic particles are removed by magnetic means to provide substantially pure preparation of said target material. (see col. 4, lines 31-38). The magnetizable metal oxide is an iron oxide (see col. 3, lines 1-2). The magnetizable particles are produced by treating with a base- NH_4OH . (see col. 8, lines 38-40). The pendant functional group of the polysaccharide is an aldehyde group (see col. 54-56). The polysaccharide is dextran. (see col. 4, lines 10-50). Molday teaches the same method for making particles as in Example 1 of the specification of the present invention. The method comprises preparing a solution by diluting ferric chloride and ferrous chloride tetrahydrate were added dropwise with agitation over a period to a solution containing concentrated ammonium hydroxide in a water bath. Aggregates were removed by 3 cycles of centrifugation in a low-speed clinical centrifuge for 5 minutes. The ferromagnetic iron-dextran particles were separated from unbound dextran by gel filtration chromatography. Five milliliters of the reaction mixture were applied to a 2.5 X 33 cm column and eluted with sodium acetate, sodium chloride. The purified ferromagnetic iron-dextran particles were collected. Since Molday teaches the same method of making colloidal aggregates of magnetizable iron oxide particles, Molday's magnetizable particles are formed of particles of crystallites of magnetizable metal oxide. (see col. 8, lines 31-50). Claims 60, 62 and 73 are not given any patentable weight because they modify limitations of the method of making in claim 54. Claims 60

Art Unit: 1641

and 62 modify the step of forming aggregates of crystallites, which is a step in the method of making. Claim 73 is a step of introducing the pendant functional group of the polysaccharide by reaction with chloroethoxyethoxyacetic acid and base, which is a step that belongs to the method of making.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 56, 63-65, 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Molday (US 4,452,773) further in view of Chagnon et al. (US 4,628,037).

Molday has been discussed above.

However, Molday fails to teach that the magnetizable particles are formed of particles of crystallites of a magnetizable metal oxide; and a mass of crystallites having a particles size of about 3 nm to about 25 nm. Molday also fails to teach that the crystallites of the magnetizable metal oxide include a coating of an organosilane bonded directly to the particles of the crystallites and wherein said coating of polysaccharide derivative is bonded to said organosilane by attaching the polysaccharide to a pendant functional group on the organosilane.

Chagnon teaches magnetic particles useful in biological applications involving the separation of molecules. The magnetic particles have a metal oxide core composed of a cluster of ferromagnetic crystals of an iron oxide. (see col. 7, lines 22-30). The

Art Unit: 1641

ferromagnetism is defined as that magnetic behavior exhibited by iron oxides with crystal size greater than about 500 Angstrom. The method of preparing the magnetic particles comprises precipitating metal salts in a base to form fine magnetic metal oxide crystals, redispersing, washing the crystals in water and in an electrolyte. The magnetic particles comprise a magnetic metal oxide core generally surrounded by an adsorptively or covalently bound organosilane coat to which a wide variety of bioaffinity adsorbents can be covalently bonded through selected coupling chemistries. The coupling chemistries include gluteraldehyde couplings; carbodimide, diazotization. (see col. 9, lines 3-12).

It would have been obvious to one of ordinary skills in the art to use clusters of ferromagnetic crystals of an iron oxide as taught by Chagnon in the method of producing the magnetic particles discussed by Molday since Molday's particles derived from iron oxide. Furthermore, it would have been obvious to one of ordinary skills in the art to add to the organosilane coating as taught by Chagnon the polysaccharide coating as taught by Molday because the hydroxyl group in polysaccharide forms a stable bond directly to the silane functional group on organosilane.

Claims 70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Molday in view of Niswender (US 4,048,298).

Molday has been discussed above.

However, Molday fails to teach the pendant functional group of polysaccharide is a carboxyl group attached to polysaccharide through a linker having at least one

Art Unit: 1641

heteroatom for every three-carbon atom in the linker; the heteroatom is Oxygen; the linker is derived from ethylene glycol, an oligoethylene glycol or a polyethylene glycol.

Niswender teaches a polymeric carrier with a suitable reactive group. The reactive groups are carboxyl, hydroxyl and primary or secondary amine groups. The polymeric material is polysaccharides, dextrin. The reactive group can be crosslinked by inclusion of a substantial amount of a polyethylenically unsaturated monomer, such as ethylene glycol dimethacrylate. (see col. 4, lines 5-45).

It would have been obvious to one of ordinary skills in the art to attach carboxyl group to polysaccharide via an ethylene glycol linker as taught by Niswender to form a polymeric coating on the magnetizable particles of Molday since these polymeric coatings are used for attaching ligands/antibody to detect target analyte in assay.

Response to Arguments

Applicant's arguments filed August 24, 2004 have been fully considered but they are not persuasive.

Applicant submits that the method of making the magnetizable particle in Molday is different from that of the present invention. In Molday's invention, magnetite is precipitated in the presence of dextran whereas in the present invention, magnetite is formed or purified before adding the coating of dextran/polysaccharide. Applicant further explains that the "one-pot" method for preparing magnetic iron-dextran microspheres would result in particles of about 50% iron, by weight, implying that they are about 30% dextran. In contrast, the claimed invention that involves forming and at least substantially purifying aggregates of crystallites of a magnetizable magnetic oxide, and

Art Unit: 1641

then coating would provide a particle dextran than Molday's particles. The two-fold greater fraction of dextran in Molday's particles may arise because dextran is incorporated into and onto, rather than simply onto, Molday's particles. Such a greater fraction of dextran on Molday's particles indicates that the percentage of iron on Molday's particle is less and thus the particle is less magnetic and would be difficult to separate, than particles produced in the claimed invention.

The claimed method now recites a process (method of making the particle) within a process of using the particle. Thus, the method of making is not given any patentable weight because the end product is the same as that of the prior arts regardless of how it was made. The results of the process of using would be the same as those of the Molday reference. Applicant's assertion about the particle formed by Molday's method is two-fold greater in iron is not supported. Even if the particles of Molday have more iron than those of the present invention, they would still be sufficiently usable in a separation method of target material from a liquid mixture.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
September 2, 2004



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~-1641
9/2/04